Missouri DEPARTMENT OF ELEMENTARY & SECONDARY EDUCATION

Missouri DHSS Department of Health and Senior Services

October 8, 2020

Missouri's BinaxNOW Antigen Testing Program for K-12 Institutions

The federal government has prioritized public and private K-12 districts/schools to receive Abbott's BinaxNOW rapid antigen test kits to test symptomatic school personnel and students for COVID-19. The Missouri Department of Elementary and Secondary Education (DESE) strongly believes that these rapid antigen tests will be instrumental in both opening schools and keeping schools open so onsite education can safely be delivered to as many students as possible. The Centers for Disease Control and Prevention (CDC) provides additional information on antigen testing here.

The Abbott BinaxNOW test is a minimally invasive anterior nasal swab test. The test must be administered by a trained health professional (e.g. nurse or doctor), and yields results in just 15 minutes without any additional equipment. The Missouri Department of Health and Senior Services (DHSS) has established a statewide order enabling school-based RNs and LPNs, or their designee, to administer the test at the point-of-care.

The CDC offers considerations for ways in which schools can help protect students and staff and slow the spread of SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19). Testing to diagnose COVID-19 is one component of a comprehensive response strategy and should be used in conjunction with promoting behaviors that reduce spread, maintaining healthy environments, maintaining healthy operations, and preparing for when someone gets sick.

Schools should carry out these strategies in a way that protects privacy and confidentiality, consistent with applicable laws and regulations. In addition to state and local laws, regulations and guidance, school administrators should follow guidance from the Equal Employment Opportunity Commission when offering COVID-19 testing to school personnel. Schools also should follow guidance from the U.S. Department of Education on the Family Educational Rights and Privacy Act (FERPA) and its applicability to students and COVID-19 contact tracing and testing.

Test Site Obligations

Public and private K-12 districts/schools that wish to receive BinaxNOW tests to administer at school must first complete the online application here. DESE will notify districts/schools when their application is approved. **For questions about the online application process, please email communications@dese.mo.gov.**

If your district/school does not have a health professional available to administer the BinaxNOW test onsite, please contact Marjorie Cole, State School Nurse Consultant at Marjorie.Cole@health.mo.gov.

To participate, schools must agree to meet the following conditions:

Prior to Using BinaxNOW Tests:

- The district/school has medical personnel available to administer the tests.
- Testing personnel will complete the required training as outlined in this guidance document prior to administering any BinaxNOW tests.
- The district/school is able to receive the tests in one central location and potentially store the maximum amount of tests requested.
- The district/school will complete the electronic reporting on-boarding process.
- The district/school will agree to use the tests only for testing symptomatic individuals (students or school personnel).
- The district/school has a process in-place for disposal of infectious waste created through the testing process.

Ongoing BinaxNOW Testing Program Requirements:

- Testing personnel will adhere to the written Instructions for Use (IFU) provided by the manufacturer in the test package insert.
- The district/school will ensure DHSS has up-to-date information on test administrators and testing locations.
- The district/school will abide by the infectious waste disposal criteria.
- The district/school will have all individuals being tested, or his/her parent/guardian, sign an authorization for testing
- Test sites must submit all required data elements to DHSS at least every 24 hours.
- Test sites must retain documentation related to this testing program for at least two years.

Please read the following information carefully for additional information about participation in the Missouri BinaxNOW K-12 Testing Program.

Information about Abbott's BinaxNOW Rapid Antigen Test Kits

The Abbott BinaxNOW rapid antigen test is intended for qualitative detection of protein antigen from SARS CoV-2 in individuals suspected of COVID-19 within the first seven days of symptom onset. This U.S. Food and Drug Administration (FDA) authorized diagnostic test does not require any instrumentation to test the samples and instead determines a COVID-19 negative or positive result using a test card. To conduct the test, health professionals insert a swab into the anterior nasal cavity.

> **For technical usage questions about the BinaxNOW™ test, contact Abbott technical support directly at ts.scr@abbott.com** or 1-800-257-9525.

Waiver to Perform Laboratory Testing

The Emergency Use Authorization supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation. Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA certified laboratories. DHSS has established a process whereby health professionals within districts/schools can administer the BinaxNOW test under a centralized CLIA Certificate of Waiver. Districts/schools will provide DHSS' BinaxNOW Lab Director with information needed for complying with the CLIA waiver through the application process.

Districts/schools **must notify the Missouri BinaxNOW Lab Director with any changes made to the information provided** in the initial DESE application, including changes in staff administering the tests and/or changes in locations administering the BinaxNOW tests. **For questions about CLIA requirements and notifications of changes, email Russ Drury at Russ.Drury@health.mo.gov.**

Test Inventory and Personal Protective Equipment (PPE)

Missouri is receiving incremental shipments of the BinaxNOW test kits. Districts/schools that choose to participate in the testing program will receive automatic, incremental shipments of tests likely not to exceed the total number of personnel and students within the district/school. Districts/schools may request a smaller number of tests through the application process if they so choose.

The district/school must select a centralized location for receipt of the test kits. Test kits, packed 40 in a box, must be stored at 35.6° to 86°F and used by the expiration date listed on the packaging. Districts/schools must have the capacity to store the maximum number of tests

requested. The district/school is responsible for distributing test kits to schools/buildings within the district/school; however only whole cases should be distributed to testing locations to ensure the control test remains with the box it is assigned. If additional test kits become available, DESE will send notification of a process to provide further inventory to districts/schools.

DHSS recognizes that school health professionals may lack adequate PPE needed for administering the BinaxNOW tests. Therefore, the PPE necessary to safely administer these tests will be provided by the state. **For further questions about test allocation email communications@dese.mo.gov.**

Training Requirements

It is very important that testing staff administer the test correctly in order to assure the highest confidence in the test results. The BinaxNOW test training video, produced by the manufacturer, provides a detailed step-by-step guide to the test process. Testing staff must watch the overview video and modules one through four before performing tests on individuals. All health professionals administering the BinaxNOW rapid antigen tests through this program must provide documentation of training to the BinaxNOW Lab Director, Russ Drury. When the district's/school's application is approved by DESE, additional information about training documentation will be provided to the primary point of contact listed in the online application. **For questions about clinical training, districts/schools may email Marjorie Cole at Marjorie.Cole@health.mo.gov.**

Use of BinaxNOW Tests

The Emergency Authorization for Use for the Abbott BinaxNOW antigen test is for testing of symptomatic individuals within seven days of symptom onset. DESE and DHSS encourages districts/schools to first use the tests for symptomatic school personnel, knowing workforce shortages are currently a key challenge in continuing to provide onsite education.

Point-of-Care Requirements

When students or personnel receiving a BinaxNOW test are suspected to have COVID-19, they should be isolated from others. Health professionals should administer this test in a space other than the school health office. The testing location should:

- Have facilities and/or products for proper hand hygiene (e.g. alcohol-based hand cleanser).
- Have appropriate waste disposal within arm's length from the patient.

Materials Needed

Test administration requires the following resources:

- PPE for the health professional using contact and droplet precautions. Recommended PPE include gown, surgical mask, protective eyewear and gloves, as well as hand hygiene products. Additional PPE guidance can be reviewed here. The PPE necessary to safely administer these tests will be included by the state.
- BinaxNOW Ag test kit.
- Copy of consent (parental or staff).
- Patient educational materials to provide information about the test and interpreting results.
- Infectious waste bags for discarding used testing materials and PPE.

Consent for Testing

Test administrators should obtain written consent for anyone they test. For those under age 18, a parent or guardian should provide written consent. A sample consent form is provided in Appendix B, but districts/schools should modify this form to meet the needs of their agency. Participating districts/schools should maintain record of signed consent forms for two years. For questions obtaining consent, the district/school should consult their legal counsel.

Evaluating the Results of Rapid Antigen Testing

Health professionals administering the BinaxNOW tests should consult the BinaxNOW COVID-19 Ag Care Procedure Card for determining the test results. Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. A positive test is diagnostic for COVID-19. People testing positive shall be instructed on isolation requirements.

Individuals with negative test results, but who are showing possible COVID-19 symptoms, should be encouraged to follow-up with their health care provider. People showing symptoms of illness, but test negative for COVID-19 should be encouraged to stay home until their symptoms have resolved, following the organization's policy for illness. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

For questions regarding possible control measures for persons who test negative but have recent exposures and symptoms of COVID-19, please contact your local public health agency. Districts/schools conducting COVID-19 testing may also wish to review School Reporting of a Positive or Suspected COVID-19 Student or Employee guidance previously shared with districts/schools. Contact your local public health agency for questions regarding case

investigation, contact tracing, and other public health control measures following a positive result.

> **For technical usage questions about the BinaxNOW™ test, contact Abbott directly at ts.scr@abbott.com** or 1-800-257-9525.

Disposal of Testing Materials

All components of the BinaxNOW test kit should be discarded as infectious waste according to Missouri regulatory requirements. A Missouri Licensed Infectious Waste Transporter can assist with this process if you do not already have an infectious waste plan in place. Find more information about the Management of Infectious Waste by Small-Quantity Generators here. Other medical waste (i.e. trash, such as PPE, that is not grossly contaminated) coming from facilities testing for COVID-19 is no different than waste coming from facilities without COVID-19 patients. CDC's guidance states that management of such medical waste should be performed in accordance with routine procedures. There is no evidence to suggest that facility waste needs any additional disinfection. Read further waste management information from the CDC here. **For questions about infectious waste disposal, please email Jonathan Garoutte at Jonathan.Garoutte@health.mo.gov.**

Documentation and Reporting of BinaxNOW Test Results

By administering BinaxNOW tests, a facility is acting as a laboratory. Laboratories are required to submit all COVID-19 test results (positive/negative/other) for tests performed in their facility to the State of Missouri. The facility is also acting as the provider. Providers are required to submit case reports to DHSS.

Facilities, including K-12 schools, which administer point-of-care tests may report the necessary information for ***both*** the laboratory report ***and*** the case report on a single comma separated values (CSV) file, which is a format-free version of a spreadsheet. Required data fields include facility information, patient demographics, lab results (both positive and negative) and basic information about symptoms. The CSV file is then uploaded to a Secure File Transfer Protocol (SFTP) site, and is auto-ingested into the state's disease monitoring platform, known as EpiTrax. This information is then immediately accessible to local and state health authorities.

To successfully submit test results through SFTP, testing sites will need:

- Reporting template from DHSS
- Access to a computer/laptop with Microsoft Excel or an alternative application that can work with Excel files
- Access to the Internet
- User name and password for the secure upload site

There are three onboarding steps to complete laboratory/case reporting:

Step 1: Once DESE approves the district's/school's application, DHSS will contact districts/schools in onboarding groups. Look for an invitation email with the following resources:

- A CSV Excel file to facilitate seamless reporting into EpiTrax, DHSS' disease surveillance system
- Electronic COVID-19 Laboratory Reporting Submission Instructions to walk through submitting files via SFTP
- A second email with your SFTP credentials

Step 2: The test site will start to submit files via SFTP. To expedite this process, the first submission may consist of test data, as it will be for validation purposes only. DHSS will review the data for accuracy and contact the district/school if any changes are necessary.

Step 3: Once DHSS validates the data, the site will go live for ongoing submissions. Properly formatted data ingests directly into EpiTrax, where DHSS and local public health agencies document and track case investigation activities.

In advance, please familiarize yourself with the instructions for how to complete the CSV appropriately, including the data elements you will be required to submit. **If you have questions about formatting your Excel files or how the process works, please contact ELR@health.mo.gov.** Please note that there are over 1,000 facilities that may receive some type of point-of-care test, so there may be some delay in the onboarding process.

Appendix A
Quick Reference Resources

Topic	Name	Contact Information
Application, Test Allotment and Shipments	DESE Communications	Comunications@dese.mo.gov
Electronic Reporting of Test Results	DHSS Electronic Reporting On-boarding Team	ELR@health.mo.gov
Waiver to Perform Laboratory Testing (CLIA)	Russ Drury	Russ.Drury@health.mo.gov
Infectious Waste Disposal	Jonathan Garoutte	Jonathan.Garoutte@health.mo.gov
Positive Case Reporting	John Bos Craig Highfill	John.Bos@health.mo.gov Craig.Highfill@health.mo.gov
Clinical Training	Marjorie Cole	Marjorie.Cole@health.mo.gov

Helpful Documents for the BinaxNOW COVID-19 Test Kit

Available materials include:
BinaxNOW COVID-19 Ag Healthcare Provider Fact Sheet (English)
BinaxNOW COVID-19 Ag Patient Fact Sheet (English and Spanish)
BinaxNOW COVID-19 Ag Procedure Card (English)
BinaxNOW COVID-19 Ag Card Package Insert (English)

Appendix B Sample Consent Form

Voluntary Testing Consent & Acknowledgement Form for _____ School District
Enclosed with this form is a notice entitled "School Reporting of a Positive or Suspected COVID-19 Student or Employee." If that notice is not enclosed, it can be located at the following hyperlink: https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/pdf/school-covid-reporting.pdf

BinaxNOW is an antigen test that detects the presence of the SARS-CoV-2, which is the virus that causes a COVID-19 infection, in about fifteen (15) minutes. The specimen for the test is collected via nasal swab. This test is completely voluntary and will not ever be administered unless this form is signed. As stated in the above notice, a positive result of this test will be immediately reported to the Local Public Health Agency ("LPHA") so that it can begin contact tracing and instituting appropriate disease control measures. The LPHA solely manages these efforts. Additionally, all test results will be shared with the Department of Health and Senior Services pursuant to state regulation.

BinaxNOW is currently only able to be administered to individuals suffering from symptoms consistent with an infection of COVID-19. A negative test result, however, may indicate that those symptoms are actually the result of a common cold, allergies, or a different illness. If symptoms consistent with an infection of COVID-19 develop or persist after a negative test result, consult with a health care provider or the appropriate LPHA to determine the best course of action.

Except as required by law, test results and testing information will be kept confidential by the school district, LPHA, and Department of Health and Senior Services.

Completing and signing this form serves as consent for the test to be performed on the named individual and is also an acknowledgment of the above statements as well as the content of the enclosed notice entitled "School Reporting of a Positive or Suspected COVID-19 Student or Employee." Upon request, this completed and signed form should be provided to the appropriate school district personnel.

CONSENT & ACKNOWLEDGMENT

Print name of person to be tested: _____
Status of person to be tested (circle): student employee other_____ (explain)
Print parent / guardian name (if applicable): _____
Date: _____
Signature of person tested or parent / guardian: _____

DISTRICT USE:
Received by (name) _____ on (date) _____
Place of test administration: _____ on (date) _____